Detection and treatment of endobronchial (pre-)malignant lesions after treatment of early stage lung cancer in COPD patients

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PRIMARY OBJECTIVE1. To assess the effect of screening with AFB and subsequent treatment of endobronchial lesions in addition to screening with CT scan on cancer free survival of COPD patients previously treated for early stage NSCLC. SECONDARY...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract neoplasms
Study type	Interventional

Summary

ID

NL-OMON35775

Source
ToetsingOnline

Brief title
ProFECT trial

Condition

- Respiratory tract neoplasms

Synonym
Lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: aanvraag EU loopt

Intervention

Keyword: Bronchoscopy, COPD, Lung cancer, Screening

Outcome measures

Primary outcome

Five-year cancer free survival

Secondary outcome

Overall five-year survival

Quality of life

Cost-effectiveness

Study description

Background summary

Patients treated for early stage lung cancer with curative intent are at risk for subsequent primary lung cancer(s). At present there is no international consensus on the follow-up of these patients. Sensitive methods for the early detection of lung cancer such as CT scan and autofluorescence bronchoscopy are currently available and primary screening trials are ongoing. It is unknown whether autofluorescence bronchoscopy (AFB) is accurate and cost-effective in secondary screening and whether early detection and treatment of subsequent endobronchial primary lung cancer(s) improves patient survival.

Study objective

PRIMARY OBJECTIVE
1. To assess the effect of screening with AFB and subsequent treatment of endobronchial lesions in addition to screening with CT scan on cancer free survival of COPD patients previously treated for early stage NSCLC.

SECONDARY OBJECTIVES
1. To assess the incidence and progression rate of endobronchial

(pre-)malignant lesions in high-risk patients.
2. To assess the effect of screening with AFB and subsequent treatment of endobronchial lesions in addition to screening with CT scan on overall survival and quality of life of COPD patients previously treated for early stage NSCLC.
3. To investigate the cost-effectiveness of screening with AFB in addition to CT scan in COPD patients previously treated for early stage NSCLC.

Study design

Randomized, open trial

Intervention

Screening with autofluorescence bronchoscopy and direct treatment in case of detection.

Study burden and risks

The burden in the intervention group consists of annual autofluorescencebronchoscopy and treatment in case of detection of a (pre-)malignant lesion. The risks (complications) of bronchoscopy and local endobronchial treatment are low (<1%). The endobronchial treatment might prolong cancer free and overall survival in the intervention arm.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

T1N0M0 or T2aN0M0 histologically proven NSCLC with a maximum tumor diameter of 4cm, treated with either anatomical surgical resection or SBRT with curative intent within the last six months. T descriptors according to the 7th edition of the TNM classification for lung cancer. ;GOLD II-IV COPD prior to resection.10

Exclusion criteria

Adjuvant chemo-, immune- or radiotherapy
Current or recent (<5 years) cancer other than lung cancer.
Chronic respiratory failure, defined as PaO2 <60 mmHg with or without PaCO2 >50 mmHg.10

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2011

Enrollment:	890
Type:	Anticipated

Ethics review

Approved WMO Date:	24-08-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36480.029.11